

MAR - 8 2012

K120044

1 510(k) Summary of Safety and Effectiveness

<i>Date Summary Prepared</i>	January 3, 2012
<i>Manufacturer/Distributor/Sponsor</i>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<i>510(k) Contact</i>	Courtney Smith Regulatory Affairs Manager Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: csmith@arthrex.com
<i>Trade Name</i>	Arthrex Univers Glenoid
<i>Common Name</i>	Shoulder Prosthesis
<i>Product Code -Classification Name</i>	KWS – Prosthesis, Shoulder, semi constrained metal/polymer, cemented
<i>CFR</i>	HSD – Prosthesis, Shoulder, hemi-humeral, metal, uncemented
<i>Predicate Device</i>	Arthrex Univers II Shoulder System – Pegged Glenoid, K083435 Arthrex Univers Shoulder Prosthesis, K010124
<i>Purpose of Submission</i>	To obtain clearance of the Arthrex Univers II XL Glenoids (larger glenoid devices) that are a line extension of the previously cleared <i>predicate</i> small, medium and large glenoids, pegged and keeled.
<i>Device Description and Intended Use</i>	The Arthrex Univers II XL Glenoids are manufactured from UHMWPE. The glenoid articular (lateral) surface is concave and is designed to articulate with the humeral head of the Univers II humeral stems. The fixation (medial) surface is convex and is designed either with a keel or with three pegs for cement interdigitation fixation. The Arthrex XL Univers II Glenoids are indicated in replacement(s) when conditions include severe pain or significant disability resulting from degenerative,

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	<p>rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.</p> <p>The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.</p>
<i>Substantial Equivalence Summary</i>	<p>The product labeling, intended use, and the technology, engineering and performance of Univers XL Glenoids are the same as previously cleared glenoid devices.</p> <p>The ASTM F 2028 mechanical testing data demonstrated equivalency of the proposed XL glenoids and the predicate device.</p> <p>The Arthrex Univers II XL Glenoids are substantially equivalent to the predicate Arthrex Univers II System – Pegged Glenoids, and the Arthrex Univers Shoulder Prosthesis glenoids in which the basic features and intended uses are the same. Any differences between the Arthrex Univers II XL Glenoids and the predicate glenoid devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the larger Arthrex Univers II XL Glenoids are substantially equivalent to the currently marketed predicate devices.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Courtney Smith
Regulatory Affairs Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

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Re: K120044

Trade/Device Name: Arthrex Univers II Glenoid Components
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: February 6, 2012
Received: February 7, 2012

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

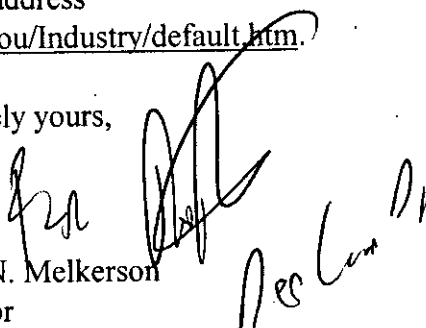
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: K120044

Device Name: Arthrex Univers II Shoulder Prosthesis – XL Glenoids

The Arthrex Univers II Shoulder Prosthesis is indicated in replacements(s) when conditions include severe pain or significant disability resulting from degenerative, rheumatoid, traumatic disease, or injury of the glenohumeral joint; non-union humeral head fractures of long duration; irreducible 2- and 4- part proximal humeral fractures; avascular necrosis of the humeral head; or, other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable.


The glenoid components are designed for cemented fixation in the joint and must only be used with an appropriate bone cement.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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